

EXHIBIT 162

From: Brantley, Eric
Sent: Thursday, April 17, 2014 10:46 AM
To: Hernandez, Tracey
Subject: SOM update
Attachments: Qualitest SOM update.ppt

Tracey,

I added slide 6 and several screenshots at the end.

Eric Brantley
Manager, Customer Due Diligence & SOM
130 Vintage Dr. Huntsville, AL 35811
256-799-7848 direct
256-799-7126 fax
ebrantley@qualitestrx.com



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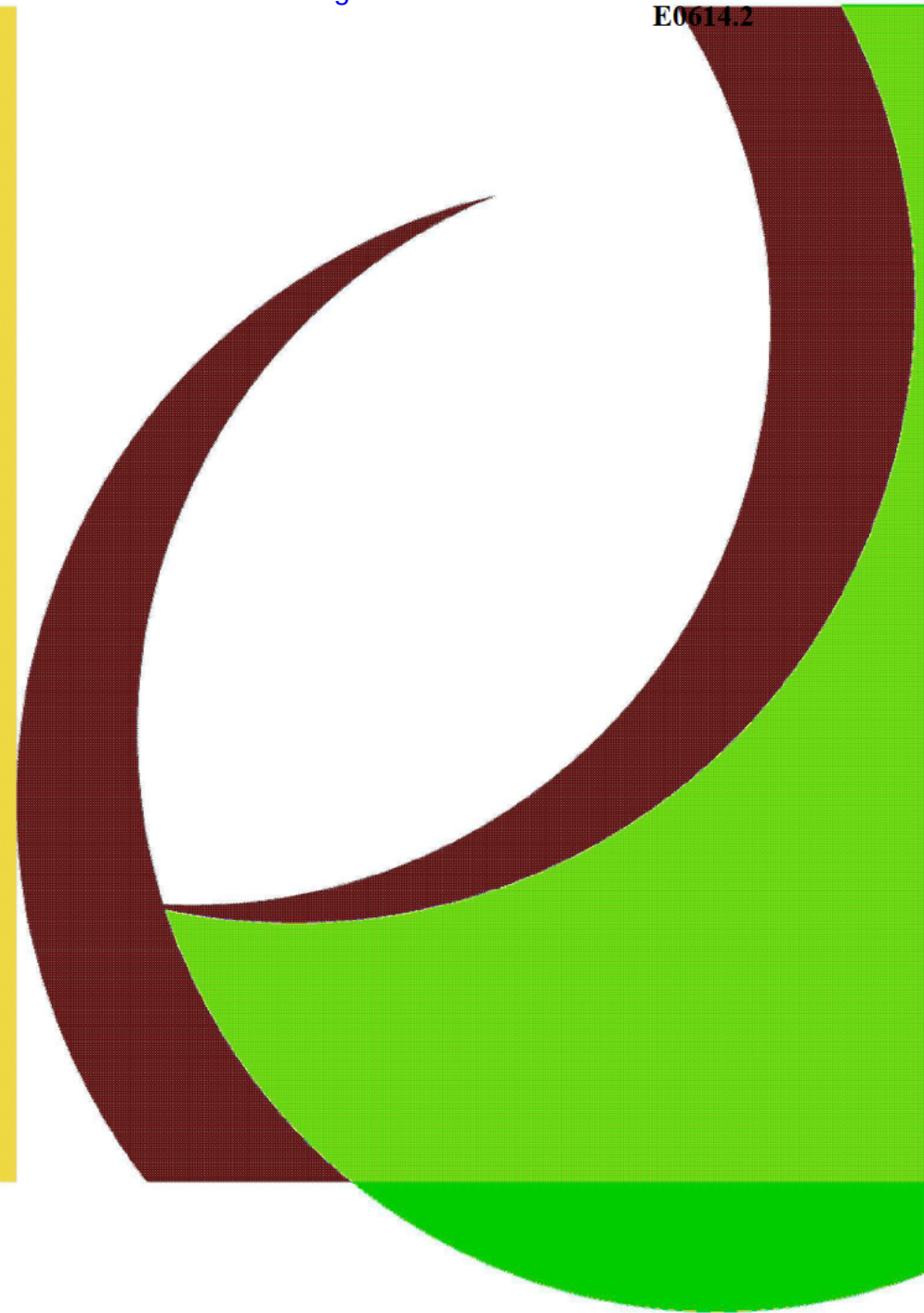
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E0614.2

Qualitest Pharmaceuticals

Suspicious Order Monitoring (SOM) Update

April 2014



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Regulation

21 CFR 1301.74(b)

- The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

SOM – The Journey That Never Ends



Drug **ENFORCEMENT** Administration

“The DEA considers itself an enforcement agency...”

“Unusual size, pattern and frequency language are disjunctive and not all inclusive.”

Alan Santos – March 10th, 2014 at HDMA conference, six weeks after leaving DEA

The Challenge:

Build and operate a system that complies with the regulation, anticipates and responds quickly to shifts in interpretations of the regulation, and avoids enforcement activity for alleged non-conformance.

The Qualitest Solution...



Know Your Customer – Retail Independent Pharmacies

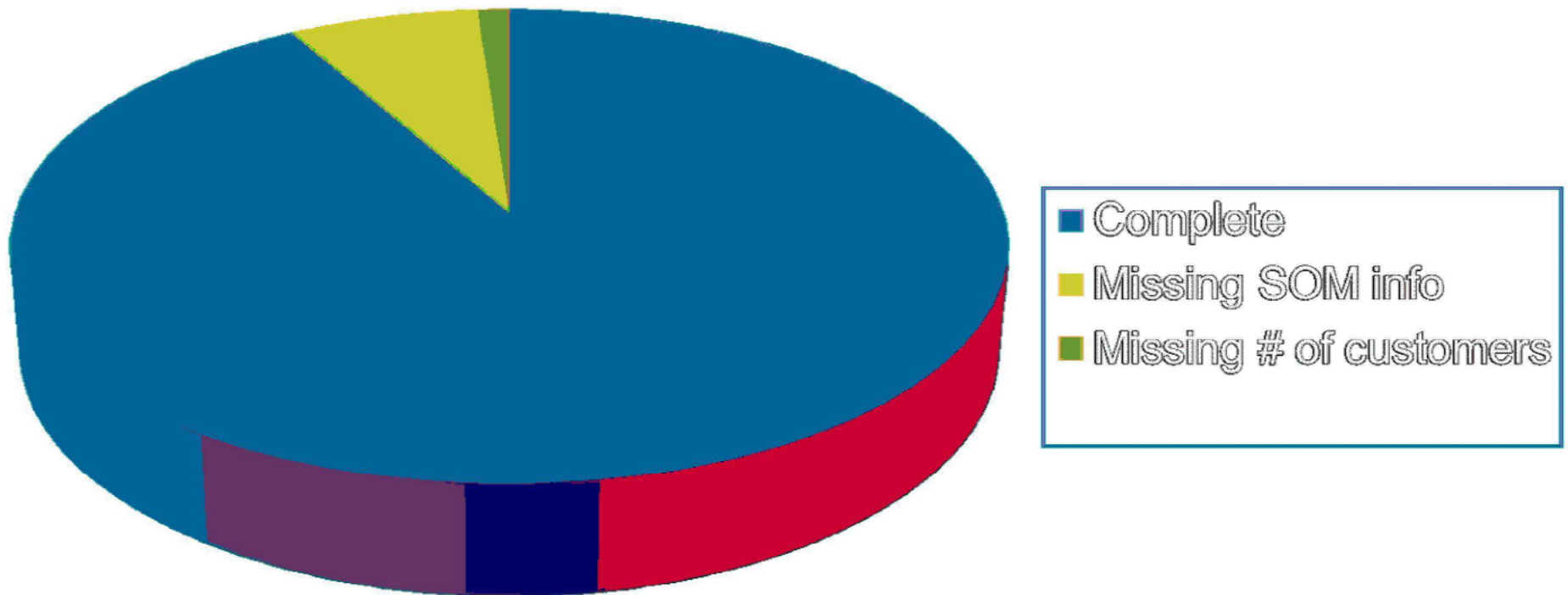
- Retail Independent Pharmacies are not allowed to order Schedule II or III Controlled Substances.
- A questionnaire is required for consideration to have the ability to order Schedule IV and V Controlled Substances.
 - 10 out of 200+ Retail independent Pharmacies currently have the ability to order Schedule IV and V Controlled Substances.
 - 21 retail independent pharmacies have completed the required questionnaire.
 - 9 Retail independent pharmacies were visited by a third party, Pharma Compliance Group (PCG).

Discontinued Controlled Substances

- The following is a sample of customers which had distribution of controlled substances ceased.
- [REDACTED]
 - 71% controlled substances, 92% of controlled substances were hydrocodone and carisoprodol, 60% paid in cash.
- [REDACTED]
 - Hydrocodone and Carisoprodol were primary controlled substances dispensed. Could not account for all carisoprodol purchased. 11,000 dosage units were purchased but only 6110 dispensed.
- [REDACTED]
 - 67% controlled substances. Only three controlled substances were dispensed: hydrocodone, carisoprodol 350mg and alprazolam 2mg, this combination is referred to as the trinity.

Know Your Customer – Wholesaler/Chain

Customer Questionnaires



Wholesaler/Chain *continued*

The following customers have not provided SOM information:

- Ahold
- Drogueria Betances
- F.W. Kerr
- Kinney Drugs
- Meijer
- Weis Markets

The following customer has not provided the # of customers serviced:

- Kaiser Permanente
- CVS Caremark (mail-order)

E0614.10

<u>Month</u>	<u>Year</u>	orders	not monitored	system cleared	cleared after review	rejected after review	orders pending	items pending
April 4-14-14	2014	1610	897	592	120	0	121	141
March	2014	2902	1800	981	119	0	121	153
February	2014	3167	1945	1063	159	0	159	170
January	2014	3308	1966	1182	160	0	160	195
December	2013	2546	1444	1026	75	1	76	91
November	2013	2789	1635	1092	34	1	35	38

An algorithm administered by Cegedim is used to identify “orders of interest” based on order history, class of trade, like customer comparison, etc.

Pended orders are checked against monthly thresholds, and the customer is contacted for additional information/justification.

If an order represents a buy-in or a multiple month order, all future orders for the drug family are locked until the required time has elapsed.



Boundaries - Retail

- Boundaries are set using [REDACTED] obtained from [REDACTED]
[REDACTED]
[REDACTED]
- The maximum boundary for a pharmacy is [REDACTED] for the number of prescriptions filled monthly. This is due to the fact that every pharmacy has a [REDACTED]
[REDACTED] It is common in the current regulatory environment for a pharmacy to have other wholesalers as well.
- Examples:
 - [REDACTED]
 - [REDACTED]
 - [REDACTED]
 - [REDACTED]
 - [REDACTED]
 - [REDACTED]

Boundaries – Wholesaler/Chain

- Boundaries are set using [REDACTED] obtained from [REDACTED]
[REDACTED]
[REDACTED]
- The boundary for a wholesaler is based on [REDACTED] [REDACTED]
This is due to multiple suppliers of product. This may change to [REDACTED]
[REDACTED] on items which Qualitest is primary or the single source.
- Chains typically receive [REDACTED] [REDACTED] due to the limited number of brands on the pharmacy shelves and the Qualitest primary position.
- For a customer to receive [REDACTED] [REDACTED], Qualitest would need to be the only brand stocked and the only supplier of the product.

Know Your Customer's Customer

- DEA's expectation is for a manufacturer to know your customer and your customer's customer. If diversion is found at the pharmacy level, the entire supply chain has a corresponding responsibility to ensure the drugs distributed are used for a legitimate medical purpose.
- Chargeback data is reviewed to gain visibility into secondary customer purchases. IQ2020 is the tool used to view chargeback data
- If suspicious quantities of controlled substances are found:
 - The customer is asked to provide due diligence information on the secondary customers in question.
 - Chargebacks can potentially be denied for lack of information or inadequate information.
 - Customer can be asked to stop distributing Qualitest item in question to secondary customer.
 - Secondary customer will be reported to DEA as a suspicious customer.

Chargeback Data

IQ - Windows Internet Explorer

https://qualitest.iq2020.com/project/Default.aspx?id=31&is=wholesale+accts+view=by+month&is=wholesale+accts+view=by+month&is=times%27s+views

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acooper@qualitestrx.com
Switch Projects Log off

Menu Sales Views Chargeback Views Help My Dashboards

Flex View Customer Profile Map View

SuperFilter Edit

Customer

✓ Wholesaler	1
Indirect Customer	14
Indirect Customer State	2
Indirect Customer City	12
✓ DEA#	14

Item

Item Family Pain/Analgesic	
✓ Item Group	1
Item	18

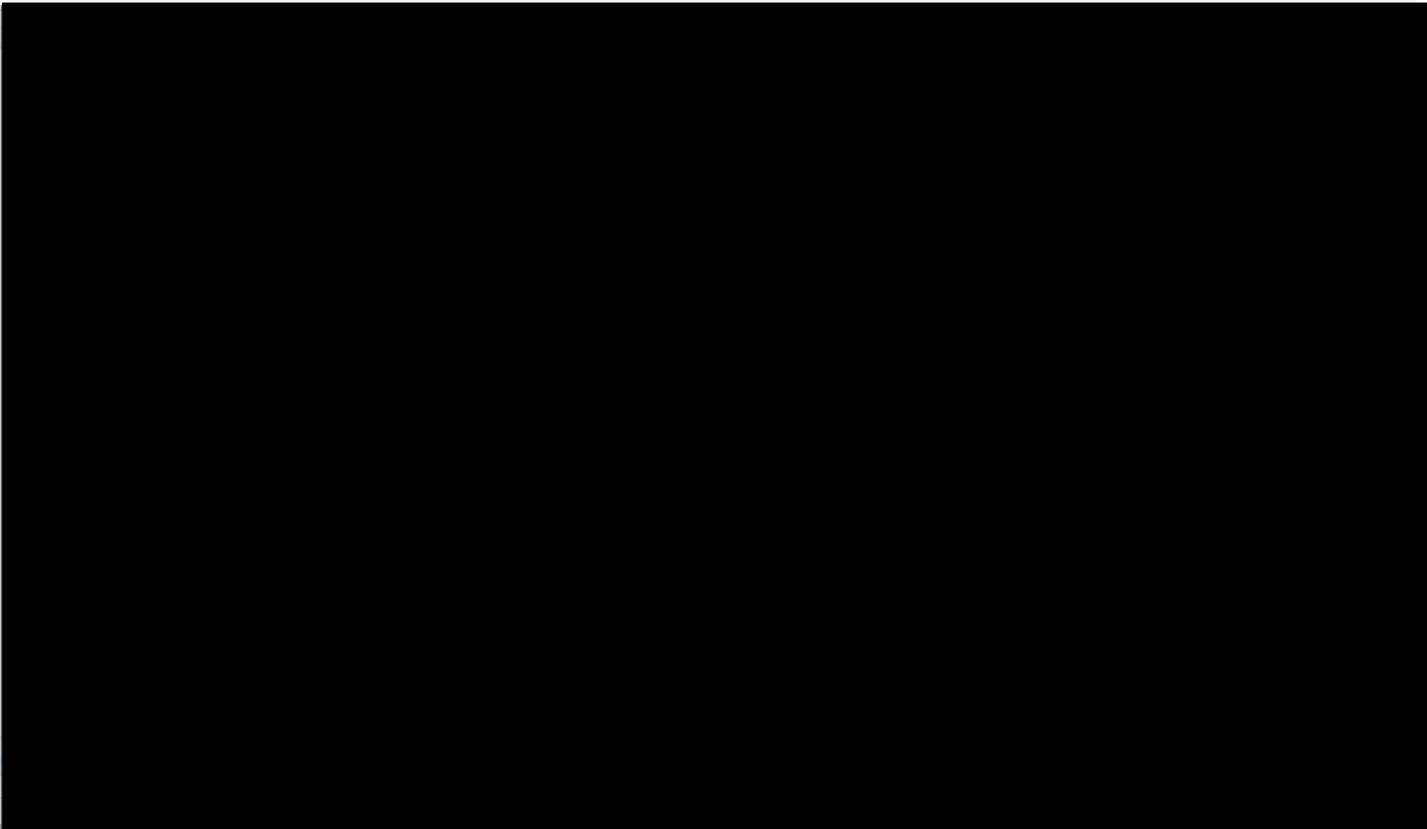
Others

Control Type	18
Class of Trade	3

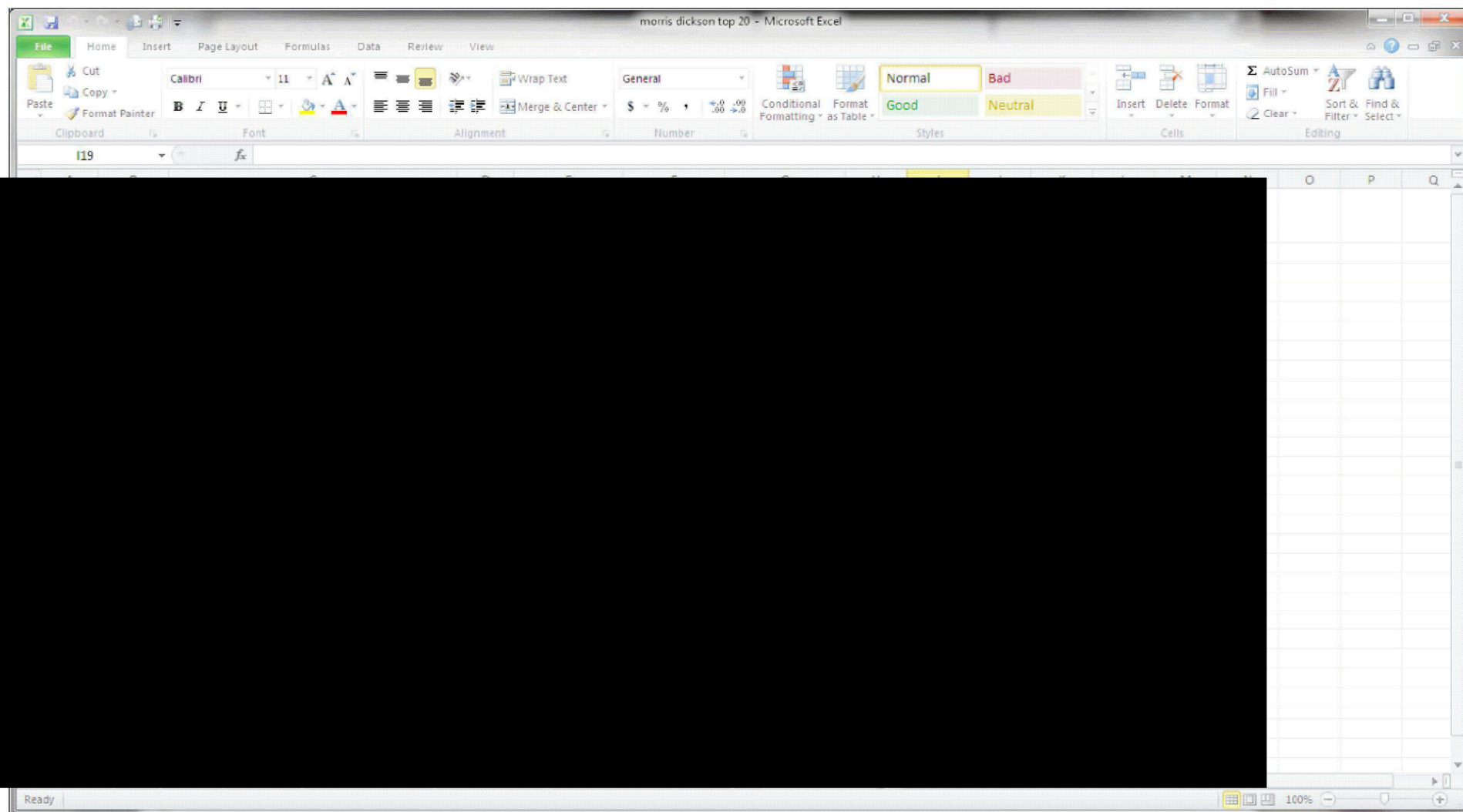
Time Period

Invoice Date	130
✓ Invoice Month	8
Credit Date	36
Credit Month	9

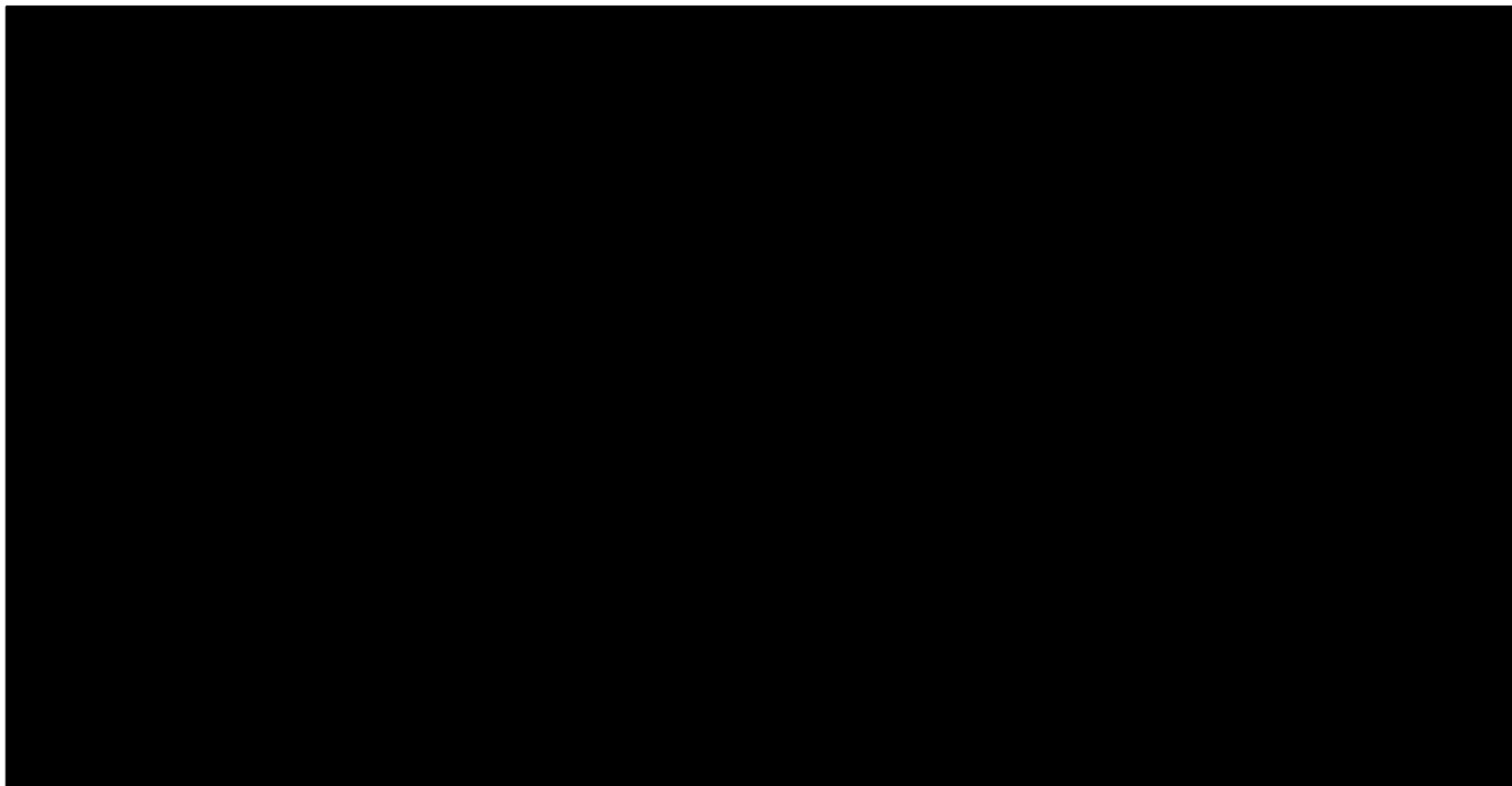
Default View Selected Items



Chargeback Data



Chargeback Data





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